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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,406	03/01/2002	Gary K. Michelson	101.0093-00000	6768

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EXAMINER

PRIDDY, MICHAEL B

ART UNIT PAPER NUMBER

3732

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/085,406

Applicant(s)

MICHELSON, GARY K.

Examiner

Michael B Priddy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-115 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-8, 10-17, 22-24, 26, 27, 37-42, 45-63, 65-76, 79, 80, 84 and 94-115 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 9, 18-21, 25, 28-36, 43, 44, 64, 77, 78, 81-83 and 85-93 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, species B in Paper No. 20040309 is acknowledged. An action on the merits of claims 1-115 follows.

Claim Objections

Claims 1-61 are objected to because of the following informalities: in line 1 of claim 1, "a trailing end" should be --trailing end--. Appropriate correction is required.

Claim 21 is objected to because of the following informalities: in line 1, "has" should be deleted. Appropriate correction is required.

Claim 89 is objected to because of the following informalities: in line 2, "diverging" should be --diverge--. Appropriate correction is required.

Claim 96 is objected to because of the following informalities: in line 1, --a-- should be inserted between "has" and "height". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-8, 10-17, 22, 23, 26, 27, 37-42, 45, 46, 48-50, 62, 63, 65-76, 79, 80, 84, 94-96, 99, 100 and 102-104 are rejected under 35 U.S.C. 102(e) as being anticipated by Cauthen (U.S. 2003/0135220). Cauthen teaches a spinal implant insertion instrument for spinal interbody prosthesis comprising: a body 12 having a leading end 17 and opposite trailing end 15, said body 12 having a first portion 18 and a second portion 37 in pivotal relationship to one another proximate said leading end 17 between an open position and a closed position, said first 18 and second 37 portions having at least in part opposed interior arcuate portions 14, respectively, said first 18 and second 37 portions defining an opening for providing protected access to the disc space and the adjacent vertebral bodies, said opposed interior arcuate portions 14 being adapted to guide therethrough a drill sized to form an implantation space across the disc space and at least in part into the adjacent vertebral bodies; and at least one disc space penetrating extension 20/35 extending from said leading end 17 of said body 12 adapted for insertion at least in part into the disc space, said extension 20/35 having a first portion 20 extending from said first portion 18 of said body, said first portion 20 of said extension having a contact surface adapted to bear against one of the adjacent endplates of the adjacent vertebral bodies, said extension having a second portion 35 extending from said second portion 37 of said body 12, said second portion 35 of said extension having a contact surface adapted to bear against the other of the adjacent endplates of the adjacent vertebral bodies, said contact surfaces of said first 20 and second 35 portions being in pivotal relationship to one another from an insertion position

to a deployed position to move the adjacent vertebral bodies apart upon movement of said first 18 and second 37 portions of said body from the open position to the closed position; wherein said opposed interior arcuate portions 14 of said first and second portions of said body are parallel to one another when said body is in the closed position; wherein said opening defined by said first and second portions of said body 12 is generally circular but, as set forth in paragraph 0039, may be elliptical; wherein said body 12 has an exterior surface that has opposed upper and lower surfaces oriented toward the adjacent vertebral bodies, respectively, said upper and lower surfaces being at least in part arcuate; wherein said exterior surface of said body has opposed side surfaces, said side surfaces being at least in part arcuate; wherein said side surfaces of said exterior surface are parallel to one another; wherein said body has an exterior surface that has a generally circular cross section along at least a portion of the length of said body but may have an elliptical cross section; wherein said first 20 and second 35 portions of said extension touch one another when in the insertion position; wherein said extension has a height between contact surfaces and a length sufficient to properly align and distance apart the adjacent vertebral bodies when in the deployed position; wherein said body 12 has an external surface at its leading end and said extension has an external surface that is at least in part coextensive with said external surface of said body 12; wherein said extension has a tapered leading end to facilitate placement of said extension into the disc space when in the insertion position; further comprising an impaction cap 24 adapted to cooperatively engage said trailing end of said body when said body is in the open position; further comprising a collar 26 threadably engaging

said trailing end 15 of said body 12 and adapted to cooperatively engage said body 12 when said body 12 is in the closed position to hold said body 12 in the closed position; wherein said body 12 has a height in the range of 6-24mm and said opening defined by said first 18 and second 37 portions of said body 12 has a height in the range of 6-24mm; further including a reamer (disclosed in line 3 of paragraph 0038) ; further including an implant driver (disclosed in lines 4-5 of paragraph 0039); and further comprising a spinal implant (line 5 of paragraph 0039).

Concerning the limitations of claims 16 and 75 requiring the body have a generally oval cross-section, it is the Examiner's view that oval and elliptical are equivalent shapes and that by teaching an elliptical cross-section, Cauthen is also disclosing an oval cross-section.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 51-61 and 105-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen in view of Bianchi et al. (U.S. 2004/0073309). Cauthen teaches all of the limitations of the present invention except said implant comprises ceramic and bone morphogenetic protein and includes a porous material.

Bianchi et al. teaches an open intervertebral spacer which, in one embodiment, comprises a biphasic calcium phosphate ceramic including tricalcium phosphate and hydroxyapatite (paragraph 0084). In claim 6 Bianchi et al. requires the implant be of a porous material. The spacer of Bianchi et al. has a greater biomechanical strength than bone dowels of the prior art and therefore avoids collapse under the intense cyclic loads of the spine prior to fusion (paragraph 0010). It would have been obvious to one of ordinary skill in the art at the time of the present invention to use the system of Cauthen to implant the spacer of Bianchi et al. because the spacer offers superior biomechanical properties and avoids failure when implanted in the spine of a patient.

Claims 24, 47, 81, 97, 98 and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen as applied to claims 23, 45, 62 and 99 in view of the following. Cauthen teaches all of the limitations of the present invention except except the contact surfaces have a length greater than one half the depth of the disc space measured from the anterior to the posterior aspect of the adjacent vertebral bodies; the bone removal device has a height in the range of 8-20 mm; the extension has a combined height when closed in the range of 6-18 mm; and the extension has a length in the range of 12-32 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct these portions of the device of Cauthen such that it had these dimensions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Allowable Subject Matter

Claims 64, 77, 78, 82, 83, 85-93 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 2, 3, 9, 18-21, 24, 25, 28-36, 43 and 44 would be allowable if rewritten to overcome the objection set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B Priddy whose telephone number is (703) 308-8620. The examiner can normally be reached on Mon.-Fri. 8 a.m. - 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael B. Priddy

Michael B. Priddy
April 30, 2004